THERMACHOICE™

Uterine Balloon Therapy

ThermaChoice UBT System Operating Manual

Gynecare inc.

technology for women's healthcare

PENGAD-Bayonne, N.J.

EXHIBIT

A (3)

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Gynecare™

THERMACHOICE™

Uterine Balloon Therapy

Thermal Balloon Ablation System

Read all directions, cautions and warnings prior to use.

This manual provides directions for using the ThermaChoice Uterine Balloon Therapy (UBT) System.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

Caution: This product contains natural rubber latex which may cause allergic reactions.

DEVICE DESCRIPTION

The ThermaChoice UBT System is a software controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use balloon catheter, a reusable controller, umbilical cable, and power cord. The ThermaChoice catheter is designed for use only with the ThermaChoice controller.

The balloon catheter is 1) connected to the controller, 2) inserted through the cervix into the uterus, 3) filled with sterile, injectable fluid (5% dextrose in water) carefully stabilizing the pressure to 160-180 mmHg pressure, and 4) activated to thermally ablate endometrial tissue by maintaining a temperature of approximately 87°C (188°F) for 8 minutes.

INDICATIONS

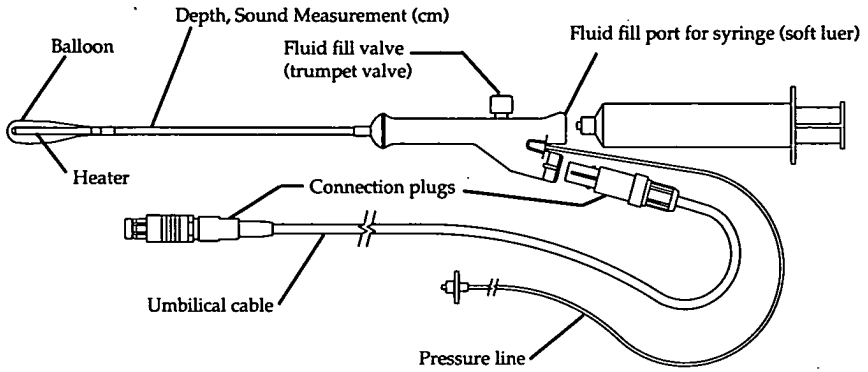
The ThermaChoice UBT system is a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

CONTRAINDICATIONS

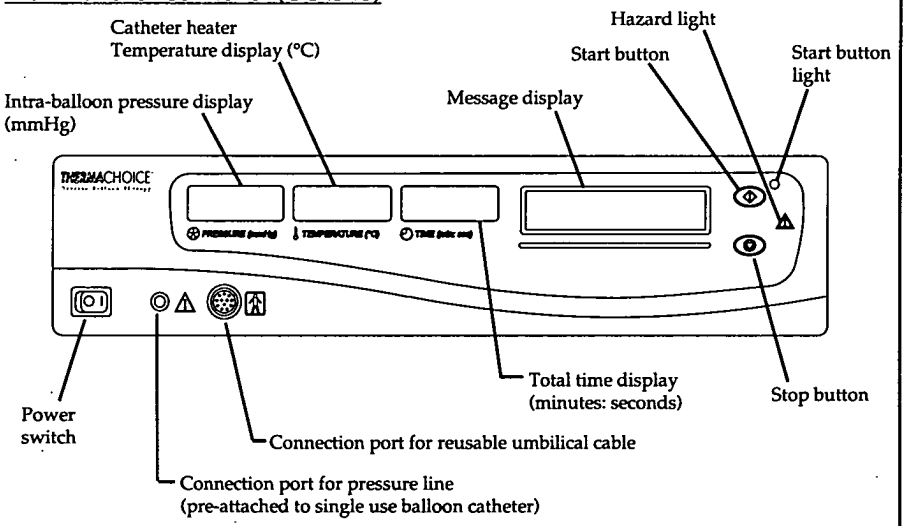
The device is contraindicated for use in:

- A patient who is pregnant or who wants to become pregnant in the future.
- A patient with a history of latex allergy or who has demonstrated a sensitivity to latex material.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium such as unresolved adenomatous hyperplasia.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.
- A patient with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
- A patient with an intrauterine device (IUD) currently in place.

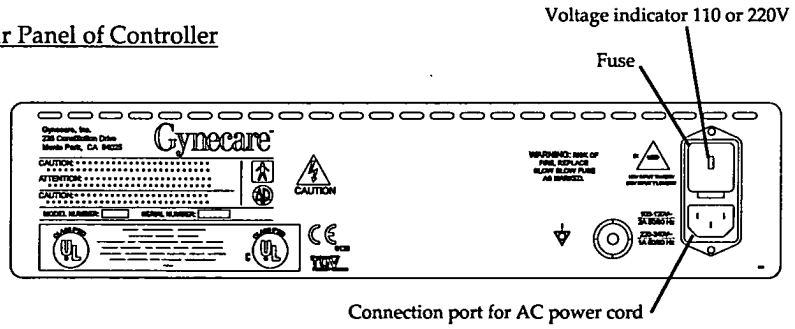
Single-Use Balloon Catheter (GC-EAC) and Umbilical Cable (GC-EAU)



Front Panel of Controller (GC-EAS)



Rear Panel of Controller



DESCRIPTION OF SYMBOLS

Front Panel of Controller

Off (power: disconnection from the mains)

On (power: connection to the mains)

Start Button

Stop Button

Indicates hazard condition and termination of procedure (see ERROR MESSAGES section) Red light; when on, attention, consult operator's manual.

INSERT CATHETER
FILL CATHETER

Message Display- displays prompts and error messages

Displays pressure inside balloon in mmHg

Displays heater temperature inside balloon in °C

Displays total running time for preheat and therapy in MINUTES: SECONDS

Rear Panel of Controller

(see SPECIFICATIONS for additional information)

Voltage indicator (110 or 220V)

Connection port for power cord

Location of Fuses; Type and value rating

Equipotentiality

Type BF Equipment

Cover to be removed by qualified service personnel only

Danger: Risk of explosion if used in the presence of flammable anesthetics!

Notified body TUV Product Services, Munich

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WARNINGS

Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury

- The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.
- Endometrial ablation using the ThermaChoice UBT System is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and fetus.
- Endometrial ablation procedures using the ThermaChoice UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity such as IUD insertion or dilation and curettage (D&C) and having adequate training and familiarity with the ThermaChoice system.
- Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- The UBT balloon catheter is for single use only — do not reuse, or resterilize.
- Do not treat patients for more than one therapy cycle in a given treatment session because of the potential for transmural injury to the uterus or injury to adjacent viscera.
- Use caution not to perforate the uterine wall when sounding the uterus or inserting the UBT balloon catheter. **If a perforation is present, the procedure should be terminated immediately.**

PRECAUTIONS

- The UBT balloon catheter, controller, and umbilical cable are designed as a system. To ensure proper function, never use other components with the UBT system.
- A starting pressure of 160 - 180 mmHg is recommended and typically requires 6-15 cc of fluid and may require as much as 30 cc. **Titration to achieve a stable pressure (no fluctuations greater than ± 10 mmHg for at least 30 sec) prior to activating the heating element is critical to proper functioning of the device. When inserting fluid, do not exceed a pressure of 200 mmHg.** Typically, pressure levels decline slowly during the course of the procedure as the uterus relaxes. If a pressure of 160 - 180 mmHg cannot be reached with 30 cc or less of fluid, or if there is a rapid drop in pressure, remove balloon catheter and check for catheter leak and/or uterine perforation. Never add additional fluid during a therapy cycle. Rapid loss of pressure during a therapy cycle may indicate a uterine wall defect is present. Adding additional fluid to the balloon may create (or exacerbate if already present) a uterine wall defect such as a perforation.
- Those patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the ThermaChoice UBT system has not been fully evaluated in patients:
  - with a large uterine cavity (>30 cc in volume or uterine sound >10 cm).
  - with a small uterine cavity (< 2 cc in volume or uterine sound < 6 cm).
  - with submucosal myomas, a bicornuate or septate uterus or a previous endometrial resection/ablation.
  - undergoing repeat endometrial ablation procedures.
  - who are post-menopausal.

ADVERSE EVENTS

In a study of 134 women, the most frequent events that have been reported following completion of the procedure include:

- Cramping/pelvic pain - Post-treatment cramping was reported in 91.8% of the patients which ranged from mild to severe as reported during the intra-operative period and immediate post-operative period. This cramping will typically last a few hours and rarely continues beyond the first day following ablation. The use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following Uterine Balloon Therapy is usually sufficient to manage cramping and pelvic pain.
- Nausea and Vomiting - Nausea and vomiting were reported for 23.9% of the patients in the immediate hours following the procedure. This may be attributed to general anesthesia, and can be easily managed with medication.
- Endometritis was reported in 2.1% of patients. All patients responded to a course of oral antibiotics.
- Post-procedure symptoms such as pain, fever, nausea, vomiting, difficulty with defecation or micturition were reported. Failure of such symptoms to resolve over a reasonable period of time warrants evaluation by appropriate medical personnel.
- Hematometra was reported in 0.6% of patients treated in clinical studies conducted outside of the United States. In all patients, the hematometra was resolved with insertion of a uterine sound.
- A single perforation of the uterus was reported in a procedure conducted outside the United States.

OTHER POTENTIAL ADVERSE EFFECTS

The following adverse effects might be expected (potential), but have not yet been observed in clinical studies of the ThermaChoice UBT System:

1. **Rupture of the Uterus**
2. **Thermal Injury to Adjacent Tissue**
3. **Heated Liquid Escaping Into the Vascular Spaces and/or Cervix, Vagina, Fallopian Tubes, and Abdominal Cavity.**
4. **Electrical Burn**
5. **Allergic Reaction to Latex**
6. **Hemorrhage**
7. **Infection**
8. **Pregnancy** - Pregnancy following endometrial ablation is dangerous to both mother and fetus.

9. **Post-ablation-tubal sterilization syndrome** - This is a complication following endometrial ablation in women who have also previously undergone tubal ligation. The pathophysiology of this condition is believed to be related to the regeneration of endometrium in the cornual areas of the uterus. Blood from these glands can flow back into the proximal fallopian tubes in cases where the lower uterine segment is extensively scarred. The proximal oviduct becomes filled with blood and fluid causing symptoms similar to those of an ectopic pregnancy.

CLINICAL TRIAL

Conclusions: At twelve months of follow-up, balloon ablation was demonstrated to be at least as safe (with fewer intraoperative complications, less use of general anesthesia, and shorter procedure times), and as effective as hysteroscopic rollerball ablation in reducing menstrual bleeding to a clinically acceptable level in menorrhagic women who had completed their childbearing. Furthermore, statistically equivalent and significant reductions in patient-reported dysmenorrhea (mild, moderate, severe menstrual cramps), PMS symptoms (mild, moderate, severe common PMS symptoms), and overall impact of menses on lifestyle (scale of 1-10; 1 = none, 10 = severe) were experienced by both groups.

Purpose: The use of balloon thermal ablation for the treatment of menorrhagia for benign causes in an anatomically normal uterine cavity was compared with rollerball electrosurgical endometrial ablation with regard to safety and effectiveness. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990;97:734-9). Success was defined as the reduction of excessive menstrual bleeding to normal flow or less. Secondary endpoints evaluated were overall percent decrease in diary scores and responses from a quality-of-life questionnaire. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used.

Methods: This randomized, prospective, multicenter clinical investigation was conducted at 14 sites using investigators highly experienced with hysteroscopic rollerball endometrial ablation. All patients were ≥ 30 years old, premenopausal, and had completed childbearing. All had an anatomically normal uterine cavity > 4 cm and < 10 cm.

Three months of documented menorrhagia for benign causes was a requirement for inclusion and was confirmed with a diary score of at least 150 points. Endometrial biopsy and pap smear were required to rule out (pre)malignant uterine disease. No uterine thinning medications could be used for three months prior to treatment, and all patients underwent a three-minute suction curettage just prior to treatment. Selection of anesthesia regimen was left to the individual investigators. Treatment success was defined as reduction in menses to a diary score less than or equal to 75 in order to assure a return to eumenorrhea. In the original Higham study, a diary score of 100 had an 86% sensitivity and an 81% specificity for true menorrhagia for benign causes as determined by chemical analysis of the saturated pads.

Description of Patients: Two hundred seventy-five patients were randomized, 260 evaluated for safety, 255 of whom were eventually treated with either ThermaChoice Uterine Balloon Therapy (131) or rollerball ablation (124). A total of 125 UBT-treated patients and 114 rollerball-treated patients were available for Efficacy Evaluation by having completed twelve-month follow-up. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (UBT 40.2 years, RB 40.9 years), race, body mass index, mean baseline diary score (UBT 552.5, RB 570.5) and other criteria.

Results:

Table 1. Effectiveness at 12 Months

	THERMACHOICE (n = 125)	ROLLERBALL (n = 114)
Study Success Rate (Diary Score ≤ 75)	80.2%*	84.3%*
Decrease to Normal Bleeding Levels or Less (Diary Score ≤ 100)	84.8%*	89.5%*
Mean Percent Decrease in Diary Scores	85.5 + 22.5**	91.7 + 12.0**
% Patients with > 90% Reduction in Diary Scores	61.6%*	68.4%*
% Patients with Diary Scores = 0	15.2%**	27.2%**
Quality-of-Life		
% Patients with Anemia Pre/Post (HCT)	29.9% / 11.6%*	29.7% / 10.6%*
Satisfaction: Very Satisfied / Satisfied	85.6% / 10.4%*	86.7% / 12.4%*
% Patients with Reduction in Dysmenorrhea	70.4%*	75.4%*
Inability to Work Outside the Home (Pre/Post-Treatment Score)	39.7%* / 4.0%*	41.9%* / 2.7%*
% Patients Reporting Severe Impact on Life Pre/Post	70.3%* / 3.2%*	78.6%* / 1.8%*

*Not statistically different (P > 0.05). **Statistically significant (P < 0.05)

Table 2. Safety at 12 Months

	THERMACHOICE (n = 134)	ROLLERBALL (n = 126)
Intra-operative Adverse Events	None (0%)	2 fluid overloads 1 cervical laceration 1 uterine perforation (3.2%)
Post-operative Adverse Events	1 post-coital bleeding 3 endometritis 1 UTI (3.7%)	1 endometritis 1 hematometra 1 PATSS[1] (2.4%)
Mean Procedure Time (minutes)	27.4**	39.6**
Cases Performed Under General Anesthesia	53.7%**	84.1%**

[1]PATSS = post-ablation-tubal-sterilization syndrome *Not statistically different (P > 0.05).
**Statistically significant (P < 0.05)

PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems including but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications, and hazards prior to the performance of any endometrial ablation procedures.

The patient selection criteria are:

- Documented diagnosis of menorrhagia for benign causes
- Completed childbearing
- Premenopausal

- Normal pap smear and endometrial biopsy
- Anatomically normal uterine cavity: standard sonography, saline infusion sonography, hysteroscopy, or hysterosalpingography within 6 months prior to performing UBT should be used to rule out submucous fibroids, large polyps, and congenital abnormalities.
- Uterine cavity depth of 6-10 cm
- Failed or contraindicated medical therapy.

PATIENT COUNSELING

As with any procedure the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation.

The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned of the potential complications which may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as bloody during the first few days; by approximately one week, serosanguinous; then profuse and watery thereafter.

PRETREATMENT PREPARATION OF PATIENT

The lining of the uterus should be thinned prior to UBT. This can be accomplished by timing the menstrual cycle to the early proliferative phase, administering pretreatment drugs such as danocrine or GnRH agonists, or performing suction or sharp curettage immediately prior to performing the endometrial ablation. The optimum pretreatment regimes have not been determined at this time.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

DIRECTIONS FOR USE

Please read all directions, cautions and warnings prior to use.

1. 0 SET-UP

1.1. The following items are required for use of the UBT System.

UBT System	Reorder # Number
1 sterile disposable UBT balloon catheter and syringe (30cc)	GC-EAC
1 umbilical cable	GC-EAU
1 controller	GC EAS
1 power cord	GC-EAP

Medical Supplies

50cc sterile injectable 5% dextrose in water (D_5W)
sterile drape for umbilical cord
tenaculum, (weighted) speculum
uterine sound, cervical dilator(s)

1.2 Open the sterile package containing the UBT balloon catheter and syringe. Disinfect umbilical cable as described at the end of this manual.

1.3 Make sure that the controller power is off before making the connection (Steps 1.4 - 1.6).

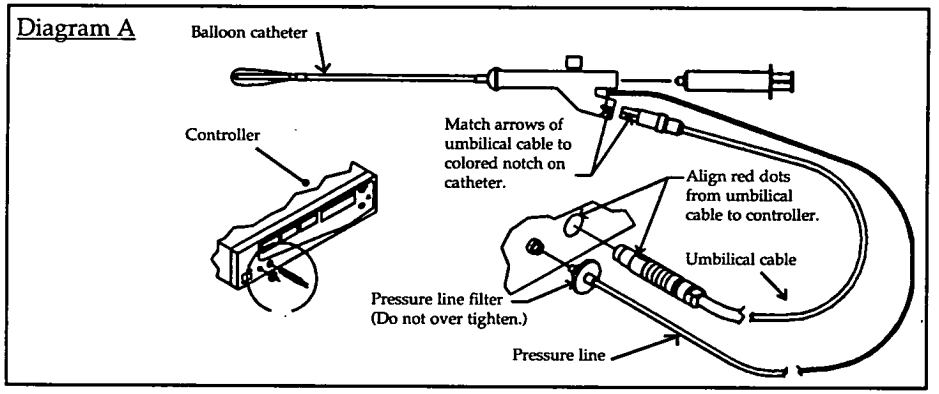
1.4 Plug the power cord into the back of the controller and into the wall outlet.

1.5 The umbilical cable includes a connector plug at each end to connect the balloon catheter to the controller. Visually inspect the cable and connector plugs to ensure there are no defects or signs of wear. Drape umbilical cable with sterile drape and attach cable to the connector at the proximal end of the balloon catheter (match arrows of cable to colored notch on catheter). Attach the opposite end of the cable to the connection port on the front panel of controller. (Align red dots from umbilical cable to controller). (See Diagram A).

Note: When oriented correctly, the cable plugs will fit into the connectors easily and securely.

1.6 Connect the pressure line (pre-attached to balloon catheter) to the connection port (luer lock) on the front panel of controller. Tighten 1/4 turn only; do not over-tighten (See Diagram A). Periodically clean the entrance of the controller's port, using a cotton swab with 50% ethyl alcohol.

Diagram A



1.7 TURN ON the controller POWER. The Message Display will read:

Message Display:
Note: N.NN = software revision level

REV. N.NN WARMING UP

After a few seconds, the Message Display will alternate between the following messages:

Message Display:

PRIME CATHETER

and

INSERT CATHETER FILL CATHETER

The pressure line MUST be connected to the controller BEFORE the balloon catheter is filled with fluid, or the device may not function properly.

2.0 CATHETER PRIMING

2.1 **FILL** the 30cc syringe with approximately 15-20cc of sterile injectable 5% dextrose in water (D_5W).

Use only sterile injectable 5% dextrose in water (D_5W). Use of other fluids may compromise system.

2.2 **CONNECT** syringe to the port in the proximal end of the balloon catheter. Do not overtighten syringe when connecting.

2.3 Point balloon catheter tip downward.

2.4 Press trumpet valve on top of balloon catheter handle and fill with 5-10cc of D_5W.

2.5 Press trumpet valve and evacuate fluid and air from balloon to a negative pressure of -150 to -200 mmHg (indicated by pressure display on controller).

Note: You may need to purge air from syringe several times to attain desired negative pressure. You must release trumpet valve to maintain negative pressure. Air should be completely evacuated to optimize the function of the device.

2.6 The negative pressure creates a low-profile balloon insertion (balloon is drawn tight against catheter tip). Do not go beyond -300 mmHg. Check that negative pressure is maintained for at least 10 seconds before proceeding.

If negative pressure cannot be maintained for 10 seconds, remove balloon catheter and replace.

3. PRESSURE TITRATION

3.1 Fill syringe to 30cc with D_5W, purge air, and connect to balloon catheter (do not overtighten).

3.2 Using appropriate sterile technique and cervical/vaginal preparation, dilate cervix to 5mm if necessary.

3.3 Measure depth of uterus.

3.4 Wet outside of balloon with D_5W.

3.5 After sounding uterus, and wetting the balloon, **SLOWLY INSERT BALLOON CATHETER** into uterus until tip is touching the fundus. Ensure depth indicated by markings on catheter is consistent with previous sound measurement. Use a tenaculum to hold cervix if necessary.

Ensure cervical dilation to 5mm and do not use excessive force during insertion, as such force can cause the balloon to tear or the catheter to perforate the uterine wall.

3.6 Press trumpet valve on top of balloon catheter and fill balloon slowly to pressure of 160-180 mmHg using 2-30cc of D_5W (Release trumpet valve to allow pressure to stabilize). Incrementally add small volumes to achieve a stable pressure (no fluctuations greater than $\pm$ 10 mmHg) of 160-180 mmHg for a minimum of 30 seconds. The pressure of the balloon against the uterine wall often precipitates uterine relaxation, thereby temporarily decreasing pressure.

For optimal results, it is extremely important to allow pressure to stabilize to 160-180 mmHg for 30-45 seconds before pressing START (◇) button. The pressure will ultimately stabilize with careful titration.

Note: Once the heater is activated, the pressure may initially rise 10-20 mmHg; the pressure may then drop slowly for the remainder of the procedure. The ending balloon pressure may be as low as approximately 100 mmHg, and is typically between 120-150 mmHg.

Note: Activation pressure for the procedure is $\geq$ 150 mmHg. The procedure cannot start until the pressure is over 150 mmHg.

Note: It is recommended that for very small uteri, pressure titration should occur towards the lower end of the range (i.e. 160 mmHg) to minimize any potential for overpressure readings during the heating process.

Do not over pressurize balloon during titration. The controller can not display pressure > 300 mmHg.

Optimal balloon volume depends on the potential volume of the uterine cavity and is typically 6-15cc at >160 mmHg (at start) and may be as great as 30cc. If pressure level cannot be reached with 30cc of fluid, remove balloon catheter and check for uterine perforation and/or balloon catheter leak. Replace balloon catheter if necessary.

4. TREATMENT

4.1 Message Display:

READY PRESS START

When a steady pressure of 160-180 mmHg is maintained, press START (◇) button on controller to activate heater.

Do not add fluid once heater is activated, as this could result in patient injury. Hold balloon catheter immobile during procedure (with valve oriented upwards).

4.2 After the start button is pressed, the controller activates the heater to achieve treatment temperature of 87°C (188°F) within 4 minutes. (This preheat cycle may take up to 4 minutes, but is usually 15-45 seconds.)

PREHEATING TO 87°C

Note: If the treatment temperature of 87°C is not reached within 4 minutes, the controller will terminate the procedure. Remove fluid, remove catheter.

4.3 Message Display:

THERAPY CYCLE 87°C 8 MIN.

Once 87°C is reached, you will hear an audible alarm that indicates automatic activation of the 8 minute therapy cycle. Time elapsed is shown on the "TOTAL TIME" display (preheat + 8 minute therapy time).

Note: Pressure may rise slightly with initial heating. It is common to then see the pressure fall gradually during procedure.

4.4 When the treatment cycle is completed, the Message Display will alternate between the following messages:

CYCLE COMPLETE REMOVE CATHETER

and

TURN POWER OFF

4.5 The controller automatically terminates the heater at the end of the treatment (cycle) and an audible alarm will sound. Total treatment time will be displayed on controller (preheat time plus 8 minute therapy time).

5. POST-TREATMENT

5.1 **Wait approximately 30 seconds for fluid to cool** and then remove fluid by drawing back on syringe while depressing trumpet valve. Remove all fluid from balloon. Remove balloon catheter. Check that entire fluid volume is with drawn.

5.2 Disconnect catheter pressure line from controller.

5.3 Disconnect umbilical cable from catheter by holding grey shell and pulling back.

5.4 Disconnect umbilical cable from controller by holding stainless steel ribbed shell and pulling back. Do not pull on the cable itself.

5.5 Discard catheter. Retain umbilical cable and disinfect for next case.

5.6 Power must be turned off before beginning another procedure.

OPERATING PARAMETERS / ALARM AND DISPLAY MESSAGES

The controller is designed to monitor time, temperature and pressure within parameters preset at the factory.

- ALERT. If the temperature and/or pressure increases or falls beyond a level pre-set at the factory, the controller will sound a short audible alert.
- HAZARD ALARM/TERMINATION OF PROCEDURE (HEATER SHUT OFF LIMITS). If the temperature and/or pressure increases or falls outside the operating parameters, the controller will sound an alarm, terminate the procedure and display an error message. Additionally, if the controller detects a system failure, the procedure will be terminated. If the procedure is terminated, the Message Display will display a message indicating the cause.

The following chart explains operating parameters for temperature, time, and pressure.

	Standard	Range	Alarm/Heater Shut Off Limits	
Temperature	87°C	75-90°C	Over Under	≥95°C for 2 sec or be- ≤75°C for 15 sec*
Pressure	Titrate to 160-180 mmHg before starting procedure; Activation Pressure (Minimum starting pressure) ≥ 150 mmHg	45-210 mmHg	Over Under	≥210 mmHg ≤45 mmHg
Time	8 minute therapy cycle after reaching 87°C (preheat phase)		Over	>4 minute pre-heat

*or failure to achieve temperature of 87°C within 4 minute preheat phase.

When parameters extend outside the normal operating range, the controller sounds an audible alert (intended only as warning signals to the clinician). These values are listed below and reside between normal operating and termination parameters (see previous chart):

		Alert (Warning)
Temperature	Over	> 90°C & < 95°C for 2 seconds
	Under	< 83°C for 2 seconds
Pressure	Over	> 200 mmHg & < 210 mmHg for 2 seconds
	Under	> 45 mmHg & < 70 mmHg for 2 seconds

ERROR MESSAGES

Under electrostatic discharge to the controller or abnormal line voltage conditions, i.e. surge and fast transients, the system may terminate the procedure. The message display may be blank or may indicate an error code. If any of these occur turn off the power to the controller and restart the procedure.

In addition to the operating messages listed in the "Directions," the Message Display also provides messages which indicate conditions under which the controller either will not begin treatment or will terminate treatment after the heating cycle has been initiated.

Prior to pressing START (◇) — the following error messages indicate conditions under which the controller will not begin therapy cycle until corrected:

MESSAGE DISPLAY	REASON	ACTION
CONNECT CATHETER	Balloon catheter and/or umbilical cable is not connected.	Connect balloon catheter. Ensure connections are secure.
CATHETER ERROR REPLACE CATHETER	Balloon catheter and/or umbilical cable is not functioning properly.	Replace balloon catheter and/or umbilical cable.
SYSTEM ERROR TURN POWER OFF	System is not functioning properly.	Return controller for repair.

After pressing START (◇) -- the following error messages indicate conditions under which the controller will terminate the procedure and disable the heating element after the therapy cycle has begun:

MESSAGE DISPLAY	REASON	ACTION
CATHETER ERROR END PROCEDURE	Balloon catheter is not functioning properly.	Remove fluid. Remove balloon catheter.
SYSTEM ERROR or HEATER ERROR and END PROCEDURE	System is not functioning properly.	Remove fluid. Remove balloon catheter. Return controller for repair.
PREHEAT ERROR or OVERHEAT ERROR or PRESSURE ERROR and END PROCEDURE	Treatment temperature and/or pressure is outside standard operating parameters.	Remove fluid. Remove balloon catheter.

WARRANTY

Gynecare, Inc., warrants the original purchase of the Gynecare UBT System Controller shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its directions for use and maintenance instructions. The obligation of Gynecare, Inc., under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Gynecare, Inc., within one year from the date of purchase, if examination shall disclose to the satisfaction of Gynecare, Inc., that the controller does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF GYNECARE. GYNECARE, INC., NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A GYNECARE CONTROLLER. THIS WARRANTY SHALL NOT APPLY TO A GYNECARE CONTROLLER OR ANY PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY GYNECARE, INC., CONTROLLER THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED GYNECARE SERVICE PERSON, MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE GYNECARE, INC. CONTROLLER AND NOT SUPPLIED AND MANUFACTURED BY GYNECARE, INC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE GYNECARE CONTROLLER WAS SOLD BY GYNECARE, INC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

Should any Gynecare, Inc. controller become inoperable after the one year period of this Warranty or should damage occur which is not covered under the terms of this Warranty, Gynecare, Inc. will, upon request, be willing to repair the controller, if possible, for an appropriate handling and repair charge.

SERVICE

Should the UBT System Controller become inoperable contact Gynecare's Customer Service Department for instructions and a return material authorization number. Clean and repackage the controller appropriately and return it for repair, servicing and/or modification to the authorized locations listed below. If the controller is not under warranty, an appropriate handling and repair charge will be established after receipt and examination of the controller.

For service, technical support or reorder information, contact in the U.S.:
Gynecare, Inc.
Ethicon, Inc.
A Johnson & Johnson Company
235 Constitution Drive
Menlo Park, CA 94025
Phone: (650) 614-2500
Toll Free: (800) 336-4963
Fax: (650) 462-6742

Note: Any device related incidence or problems which are felt to represent a safety issue, should be reported to Gynecare's Customer Service Department or Authorized European Representative.

AUTHORIZED EUROPEAN REPRESENTATIVE

ETHICON France
une divson ETHNOR S.A.
192 Avenue Charles De Gaulle
92523 Neuilly sur Seine Cedex
France
Tel: 01/46 41 59 90

ETHICON Gmbh & Co. KG
Robert-Koch-Strasse 1
D-22851 Norderstedt
Deutschland
Tel: 040/52 97-01

ETHICON Limited
PO Box 408
Bankhead Avenue
Edinburgh EH11 4HE
United Kingdom
Tel: 0131-453 5555

ETHICON S.P.A.
Via del Mare 56
00040 Pomezia
Roma
Italia
Tel: 06/911 944 32

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

Reorder Number	Description
GC-EAS	UBT System Controller
GC-EAC	UBT Balloon Catheter (sterile, single-use)
GC-EAU	UBT Umbilical Cable (reusable up to 20 applications)
GC-EAP	UBT Power cord (specify country)
GC-EAM	UBT System Manual
GC-EAI	UBT Instruction card

SPECIFICATIONS (CONTROLLER AND UMBILICAL CABLE)

Power Requirements	110 to 120 V; 50/60 Hz; 2A; 3-wire grounded system or 220-240V; 50/60 Hz; 1A; 3-wire grounded system
Mains Fuses	110-120VAC, 5x20mm T3A 250V Slow blow 220-240VAC, 5x20mm T1.6A 250V Slow blow
Heater Fuses	T5A 250V
Dimensions	Height 10.2cm (4in.), width 41.2cm (16.25in.), depth 37.0cm (14.56 in.)
Weight	6.9 kg (15.3 lb) (controller only)
Case	Aluminum and impact-resistant plastic
Umbilical Cable	Length 152 cm (60 in.)

MAINTENANCE

1.0 CALIBRATION:

Every time the UBT system is powered up, the controller zeros out the offsets that may be present on the measurement circuitry, and therefore automatically provides a single point calibration. In addition, the pressure sensor utilized in the controller is internally calibrated and temperaure compensated and is accurate and stable over the operating range. These sensors are of differential type, and therefore measure the balloon pressure relative to the outside atmosphere. In addition to the internal means of calibration, it is possible to ensure the proper operation of the system against other calibrated devices. This procedure is recommended to be performed on an annual basis. The procedure also needs to be carried out if it is believed that the system is behaving unexpectedly.

Note: There are no calibration adjustments on the controller. If the unit does not meet the calibration requirements, it needs to be sent back to the manufacturer.

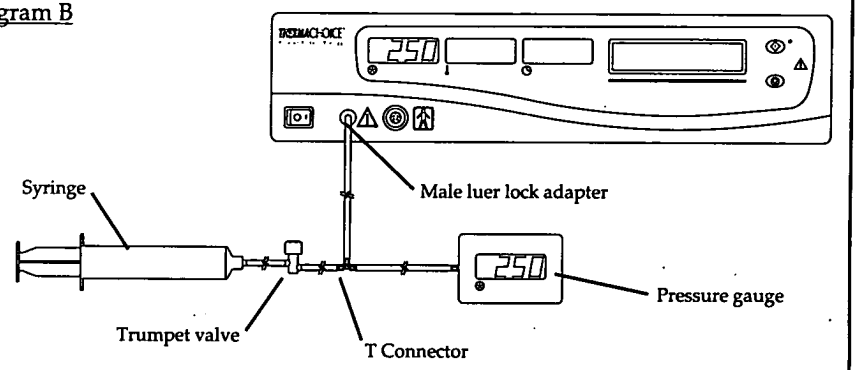
1.1. PRESSURE CALIBRATION

1.1.1. Equipment List

The following equipment list or equivalent is needed to perform the procedure:

1. Pressure meter: DigiMano model DPM 2000PS. NETECH Corporation, 60 Bethpage Drive, Hickville, NY 11801, Telephone: (800) 547-6557/ (Any calibrated, NBS traceable pressure gauge with a range of at least ± 6 psi can be used).
2. Syringe: PN 309662, Becton-Dickinson. State Surgical Supply, 3380 Vincent Rd. # C, Pleasant Hill, CA 94523, Telephone: (510) 284-1060.
3. Trumpet valve: PN S5402601, Braun Medical, Inc., 824 Twelfth Ave, PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.
4. T connector: PN T20-1, Value Plastics, Inc., 3350 Eastbrook Dr., Fort Collins, CO 80525, Telephone: (970) 223-0953.
5. Tubing: 0.093 ID, 0.156 OD, Norton Performance Plastics Corp, PO Box 3660, Akron OH 44309-3660, Telephone: (800) 798-1539.
6. Male luer lock adapter: PN B0850402, Braun Medical, Inc., 824 Twelfth Ave., PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.

Diagram B



1.1.2. Procedure

1. With no attachments to the luer lock, apply power to the controller. The pressure display should read 0±10 mmHg.
2. Assemble the digital pressure gauge, the tubing, the T connector, the trumpet valve, the male luer lock adapter, and the syringe as shown in Diagram B, and connect to the connection port (luer lock) of the controller.
3. While depressing the trumpet valve, apply vacuum to the system using the syringe until the gauge reads approximately -250 mmHg.
4. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.
5. While depressing the trumpet valve, apply pressure to the system until the reading on the digital display meter indicates a pressure of approximately 250 mmHg.

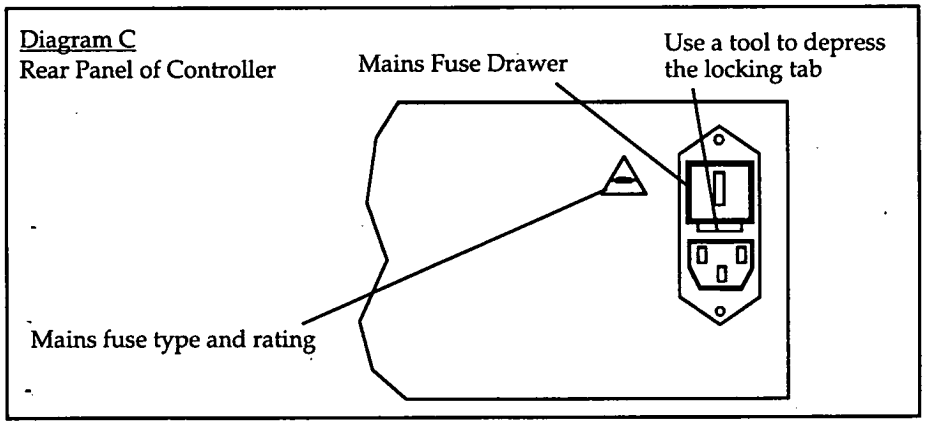
6. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.

1.2. TEMPERATURE CALIBRATION

1. Obtain a calibrated digital or glass thermometer.
2. Place this thermometer in close proximity to a new UBT catheter tip and allow them to come to thermal equilibrium with the ambient.
3. Connect the catheter to the controller using the umbilical cable as described earlier in the manual.
4. Power up the controller.
5. Note the thermometer reading and compare to that of the controller. The readings should be within ± 5 degrees Celsius.
6. Insert the balloon end of the catheter along with the thermometer in 80-90 degree Celsius water.
7. Allow a few minutes for the catheter and the thermometer to come to thermal equilibrium.
8. Compare the two temperature readings. They should be within ± 5 degrees Celsius.

2.0 FUSE REPLACEMENT:

Fuse: In the event of a main fuse failure, turn off the power and unplug the rear of the controller to allow fuse access. Using a tool such as a screwdriver, remove the fuse drawer by depressing the locking tab. See Diagram C below:



Replace both fuses with the same type and rating as specified on the rear of the controller. Reinsert the fuse drawer until the locking tab snaps into place. Reconnect the power cord and restore power to the controller. If a fuse fails again, disconnect all power to the controller and return it to Gynecare.

All other service must be performed by appropriately qualified technical personnel. Field repair, other than the controller's external fuse replacement voids all warranties and may not be performed without express authorization from Gynecare.

3.0 CLEANING: CONTROLLER SYSTEM

It is good practice to routinely clean the exterior surface of the device.

1. Disconnect all umbilical cables and unplug the power cord from the wall outlet before cleaning.
2. Use a cloth dampened with 50% water and 50% isopropyl alcohol, or a mild, nonabrasive detergent (such as commercially available dish cleaning liquid) mixed with water.
3. Periodically clean the entrance of the controller's port (luer lock) using a cotton swab with 50% isopropyl alcohol.

Do not autoclave, ETO sterilize, or immerse the controller or umbilical cable in a liquid. Do not allow liquids to enter the controller during cleaning.

4.0 DISINFECTION: UMBILICAL CABLE

The UBT Umbilical Cable is packaged non-sterile. After each use, the cable should be disinfected. To disinfect, wipe down the cable with a damp cloth using a solution of 50% water and 50% isopropyl alcohol. Use only 50% water and 50% isopropyl alcohol. Ensure that the cable and connectors are completely dry. Inspect the cable and the connector plugs before each use for signs of wear and replace if necessary. The umbilical has been validated for 20 cycles. Following 20 uses, discard the cable, and replace.

5.0 POWER CORD

Users in North America operating from a nominal 120 Vac system must select a Type SJT, SJTO, SJO, or SJE, Hospital Grade cord set. The power supply cord must be marked "Grounding Reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only"".